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Washington, D.C. 20231

David J. Levy, Ph.D.
Patent Counsel
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,019,583

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,019,583, which claims the human drug product ULTIVA™ Injection (remifentanil hydrochloride) and a method of use of the human drug product ULTIVA™, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 512 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 512 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of February 12, 1997 (62 Fed. Reg. 6549). Under 35 U.S.C. § 156(c):

$$\begin{aligned} \text{Period of Extension} &= \tfrac{1}{2}\,(\text{Testing Phase}) + \text{Approval Phase} \\ &= \tfrac{1}{2}\,(1{,}920 - 348) + 302 \\ &= 1{,}088 \text{ days} \end{aligned}$$

Since the regulatory review period began June 14, 1990, before the patent issued (May 28, 1991), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 14, 1990 to May 28, 1991 is 348 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,088 days, would extend the patent from February 15, 2009 to July 12, 2010, which is beyond the 14-year limit (the approval date is July 12, 1996, 14 years after the approval date is July 12, 2010). The period of extension is thus limited to July 12, 2010, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, February 15. 2009, to and including July 12, 2010, or 512 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,019,583
Granted:	May 28, 1991
Original Expiration Date[1]:	February 15, 2009
Applicant:	Paul L. Feldman et al.
Owner of Record:	Glaxo Wellcome Inc.
Title:	N-Phenyl-N-(4-Piperdinyl)Amides Useful as Analgesics
Classification:	514/327
Product Trade Name:	ULTIVA™ Injection (remifentanil hydrochloride)
Term Extended:	512 days
Expiration Date:	July 12, 2010

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Senior Legal Advisor/Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: ULTIVA™ Injection
(remifentanil hydrochloride)
FDA Docket No.: 96E-0385

[1] Subject to the provisions of 35 U.S.C. § 41(b).